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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,602	02/22/2005	John Hadden	3115.00066	4753

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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
04/25/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,602	HADDEN ET AL.	
	Examiner	Art Unit	
	AMY JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *24* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *24* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 2/27/12 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/12 has been entered.

Claim 24 is amended.

Claim 24 is pending and is under examination.

2. In view of Applicant's amendment to the claims, the rejection under 35 U.S.C. 112 first paragraph is withdrawn.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,614,504, March 25, 1997.

The '504 patent teaches a method of enhancing the immune response to a vaccine comprising administering the vaccine with an adjuvant formulation comprising inosine 5-monophosphate compounds, including MIMP (i.e. a protected IMP compound, see column 1, 6, 9, and, in particular). The '504 patent teaches administering the IMP compounds to treat influenza (see column 14, in particular). The '504 patent teaches measuring a response to the vaccine by performing proliferation assays in response to viral antigen (i.e. detecting a T cell response, see column 17, in particular). The '504 patent also teaches measuring an enhanced DTH response and T cell activation and cytokine secretion in response to IMP compounds (i.e. detecting a T cell response, see column 18-19, in particular). The '504 patent teaches that the IMP compound can

enhance the DTH response to an antigen that is mediated by helper T cells (see columns 3—32, in particular). In Example 10, the '504 patent teaches treating with influenza virus in combination with MIMP. An influenza virus inherently comprises influenza proteins and peptides and can be considered a "vaccine". The '504 patent also teaches that MIMP can be administered in combination with a subinfection dose of influenza virus (i.e. a virus or "influenza vaccine") to protect form subsequent challenge with the virus (see column 17, in particular). The '504 patent also teaches administering MIMP as an adjuvant in combination with any commercially available vaccine for treating viral infection. (see columns 16, in particular). The '504 patent teaches influenza vaccines that are used commercially, and it is well established that said vaccines comprise protein (see columns 4, 12, and 14). The '504 patent teaches that said influenza vaccines can be ineffective alone (see column 4, in particular).

Applicant's arguments filed 2/27/12 have been fully considered, but they are not persuasive.

Applicant argues that the '504 patent only disclosed administering an IMP compound alone or in combination with squalene, and does not disclose administering an influenza vaccine.

As noted above, the '504 patent teaches embodiments comprising administering an influenza vaccine.

Applicant further argues that the '504 patent describes only a general T cell stimulation, and does not show a T cell response to influenza. Applicant concludes that without showing that IMP provides a T cell response specifically to influenza, the '504 patent does not disclose the method of the present invention.

The '504 patent teaches that after administration of viral vaccine combined with an IMP compound, proliferation assays in response to viral antigen can be performed in order to determine if the subject has been successfully immunized (see column 17, 5th full paragraph). It is well established that T cells proliferate in response to antigen stimulation in successfully immunized subjects, and the method disclosed by the '504 patent would inherently measure T cells proliferating specifically to the viral antigen. Moreover, the '504 patent teaches that MIMP acts to stimulate T cells and induce Th1

cells (see column 18, in particular).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diepersloot et al., 1987, in view of U.S. Patent 5,614,504, March 25, 1997 (of record).

Diepersloot et al. teach a method of vaccinating a subject to treat influenza comprising administering an influenza vaccine comprising influenza proteins (see page 343, in particular). Diepersloot et al. teach measuring the T cell response to influenza vaccine by performing a DTH reaction in the vaccine treated subjects (see page 398 and 400, in particular). Diepersloot et al. teach that antibody formation against influenza antigen is a T cell dependent phenomenon, and an insufficient T cell responses can impair the response to influenza vaccination (see page 400, in particular).

Diepersloot et al. do not teach administering an IMP compound in combination with the influenza vaccine.

The '504 patent teaches a method of enhancing the immune response to a vaccine antigen comprising administering the vaccine with an adjuvant formulation comprising inosine 5-monophosphate compounds, including MIMP (i.e. a protected IMP

compound, see column 1, 6, 9, and, 16 in particular). The '504 patent teaches that the IMP compounds can treat influenza (see column 14, in particular). The '504 patent teaches measuring a response to the vaccine by performing proliferation assays in response to viral antigen (i.e. detecting a T cell response, see column 17, in particular). The '504 patent teaches that the IMP compound can enhance DTH response to an antigen mediated by T helper cells (see column 30, in particular). The '504 patent teaches that the IMP compound particular act on T cells to activate them (see columns 17-18, in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer an IMP compound as an adjuvant, as taught by the '504 patent, using the influenza vaccine taught by Diepersloot et al. The ordinary artisan at the time the invention was made would have been motivated to do so since the '504 patent teaches that the IMP compound can act as an adjuvant to enhance the immune response to viral vaccine antigens, and preferentially acts on T cells and increases DTH response.

5. Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins et al., 1996, in view of U.S. Patent 5,614,504, March 25, 1997 (of record).

Higgins et al. teach a method of vaccinating a subject to treat influenza comprising administering an influenza vaccine comprising influenza proteins (see page 479, in particular). Higgins et al. teach measuring the proliferative T cell response to influenza vaccine antigen as a means of assessing the immune response to the vaccine antigens. Higgins et al. teach that administration of vaccine antigens in combination with an adjuvant can enhance the T cell proliferative response and may also increase antibody titers due to increase T cell help available to stimulate B cells s9ee page 482, in particular).

Higgins et al. do not teach administering an IMP compound as an adjuvant in combination with the influenza vaccine.

The '504 patent teaches a method of enhancing the immune response to a vaccine antigen comprising administering the vaccine with an adjuvant formulation

comprising inosine 5-monophosphate compounds, including MIMP (i.e. a protected IMP compound, see column 1, 6, 9, and, 16 in particular). The '504 patent teaches that the IMP compounds can treat influenza (see column 14, in particular). The '504 patent teaches measuring a response to the vaccine by performing proliferation assays in response to viral antigen (i.e. detecting a T cell response, see column 17, in particular). The '504 patent teaches that the IMP compound can enhance DTH response to an antigen mediated by T helper cells (see column 30, in particular). The '504 patent teaches that the IMP compound particularly act on T cells to activate them (see columns 17-18, in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the IMP adjuvant taught by the '504 patent, in the method of vaccination and analysis of the T cell response taught by Higgins et al. The ordinary artisan at the time the invention was made would have been motivated to do so since the '504 patent teaches that the IMP compound can act as an adjuvant to enhance the immune response to viral vaccine antigens, and preferentially acts on T helper cells.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY JUEDES whose telephone number is (571)272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Kolker can be reached on 571-272-3181. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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